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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/862,404	05/21/2001	Douglas T. Dieterich	144002-2001	8918

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EXAMINER	
DEBERRY, REGINA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 03/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No 09/862,404	Applicant(s) DIETERICH, DOUGLAS T.
	Examiner Regina M. DeBerry	Art Unit 1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *13-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 7-12* is/are rejected.

7)☒ Claim(s) *6* is/are objected to.

8)☒ Claim(s) *1-16* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Status of Application, Amendments and/or Claims

The information disclosure statement filed 09 October 2001 (Paper No. 4) was received and complies with the provisions of 37 CFR §§1.97 and 1.98. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Applicant's election with traverse of Group III (claims 2 and 3) in Paper No. 6 is acknowledged. The traversal is on the grounds that the Groups designated by the Examiner fail to define methods and compositions warranting separate examination and search.

Applicant's arguments have been considered and deemed partly persuasive regarding the relationship and overlap of methods of treating ribavirin or ribavirin and interferon-alpha induced anemia and hepatitis C virus. The Examiner will rejoin Groups II (claims 1, as it is drawn to administering EPO, 8-12), III (claims 2 and 3) and IV (claims 4-7).

Claim 1, as it is drawn to administering a vector that expresses EPO will stay in Group I because contrary to Applicant's assertion, the claim reads on *gene therapy*. Gene therapy is separate class, a separate status in the art and a different field of search.

The following Groups WILL NOT be examined in this application but will be rejoined: Groups V (claim 13-15) and VI (16). Contrary to Applicant's assertion, the products of Groups V and VI can be practiced in different methods from those claimed in Groups I-IV.

A search is directed to references that would render the invention obvious, as well as references directed to anticipation of the invention, and therefore requires a search of relevant literature in many different areas of subject matter. While the added cost to the Applicants to file divisional applications is truly regretted, it is beyond the resources of the USPTO to permit examination of multiple inventions in a single application.

The requirement is still deemed proper and is therefore made FINAL. Claims 13-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6.

Claims 1-12 are under examination.

Claim Objections

Claims 1, 3-6, and 13 are objected to because of the following informalities:

Claim 1 encompasses a non-elected invention (method of administering a vector that expresses EPO *in vivo*) and requires amendment to limit to elected invention. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Appropriate correction is required.

Claims 3-5 are objected to because of the misspelling of "ribivirin".

Claim 6 is objected to for depending from a rejected claim.

Claim 13 is objected to because the claim does not end with a period.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is drawn to a method for treating hepatitis C (HCV) and for treating ribavirin or ribavirin and interferon-alpha induced anemia employed in treating said HCV in a patient in need thereof by administering erythropoietin to the patient subcutaneously for at least about 12. The instant claim is indefinite in the recitation of "12". It is unclear if the treatment is for 12 minutes, hours or days.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 1 rejected under 35 U.S.C. 102(a) as being anticipated by Bruchfeld *et al.* (Journal of the American Society of Nephrology, September, 2000, Vol., 11, No. Program and Abstract Issue, pp. 57A.). The instant claim is drawn to a method for treating hepatitis C in a patient thereof comprising administering ribivirin (RBV) or RBV and interferon-alpha (IFN), wherein the improvement comprises administering

erythropoietin (EPO) concomitantly or sequentially or via co-administration with the RBV or with the RBV and IFN.

Bruchfeld teaches the standard therapy for chronic hepatitis C (HCV) is interferon-alpha and ribavirin. Bruchfeld teaches the administration of EPO in HCV patients being treated with RBV and IFN. Bruchfeld teaches that ribavirin induced anemia was managed with erythropoietin (EPO).

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Weisz *et al.* (IDS#BW, Paper No. 4). The instant claim is drawn to a method for treating hepatitis C in a patient thereof comprising administering ribivirin (RBV) or RBV and interferon-alpha (IFN), wherein the improvement comprises administering erythropoietin (EPO) concomitantly or sequentially or via co-administration with the RBV or with the RBV and IFN.

Weisz teaches the administration of RBV, IFN and EPO in patients co-infected with HIV and HCV. Weisz teaches that RBV induced anemia can be successfully treated with EPO.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2 –5, 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bruchfeld *et al.* (Journal of the American Society of Nephrology, September, 2000, Vol., 11, No. Program and Abstract Issue, pp. 57A.) in view of Niitsu *et al.* (U.S. Patent No. 6,268,336 B1).

The teachings of Bruchfeld are described above. In addition, Bruchfeld teaches the standard therapy for chronic hepatitis C (HCV) is interferon-alpha and ribavirin for 6-12 months (claims 4-5). Bruchfeld teaches the administration of RBV, IFN and EPO patients with HCV genotype 1 (claim 7). Bruchfeld teaches the administration of EPO dosages that overlap with the instant claims (claims 9-10). Bruchfeld teaches that ribavirin induced anemia was managed with erythropoietin (EPO). It is assumed that the patient population of Bruchfeld is HIV negative (claim 11). Bruchfeld does not teach liquid preparations or routes of administration of EPO.

Niitsu teaches administration of EPO to treat anemia caused by venesection in hepatitis C patients (column 1, lines 52-60; column 2, lines 17-21 and column 3, lines 44-55). Niitsu teaches that EPO is dissolved in a saline for administration (liquid preparation of EPO) (column 3, lines 21-30) (claims 2-3, 8). Niitsu teaches administration of EPO units that overlap with the instant claims (column 3, lines 34-43) (claims 9-10). Niitsu teaches that hepatitis C patients were subjected to weekly venesection and after every venesection, EPO was subcutaneously administered

(claim 9).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the instant invention regarding treatment of HCV and RBV and IFN induced anemia comprising administering RBV and IFN and the subcutaneous administration of EPO in patients. The motivation and expected success is provided by Bruchfeld who teaches that ribavirin induced anemia was managed with administration of EPO in HCV patients and Niitsu who teaches the subcutaneous administration of EPO to treat anemia in HCV patients.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weisz *et al.* (IDS#BW, Paper No. 4) in view of Niitsu *et al.* (U.S. Patent No. 6,268,336 B1). The teachings of Niitsu are described above. Niitsu does not teach the administration of RBV, IFN and EPO in patients co-infected with HCV and HIV.

Weisz teaches the administration of RBV, IFN and EPO in patients co-infected with HIV and HCV. Weisz teaches that RBV induced anemia can be successfully treated with erythropoietin.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the instant invention regarding administering RBV and IFN and the subcutaneous administration of EPO in patients co-infected with HCV and HIV. The motivation and expected success is provided by Weisz who teaches that RBV induced anemia can be successfully treated with erythropoietin in patients co-infected

with HCV and HIV and Niitsu how also teaches the subcutaneous administration of EPO to treat anemia in HCV patients.

Conclusion

No claims are allowed.

Claims 1-5, 7-12 are rejected.

Claim 6 is objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on Mondays-Fridays 8:00 a.m. - 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Kemmerer

RMD
February 28, 2003